REMARKS/ARGUMENTS

The Examiner's attention to the present application is noted with appreciation. Applicant acknowledges the restriction requirement.

Claims Rejections 35 U.S.C. § 112

Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, second paragraph -- Office Action paragraph numbered 4. It is asserted that an "essential step" is omitted, "correlating the reactiviation with the effectiveness of the tested composition for the indicated function." It is submitted that this "step" is inherent in step g) of claim 1 ("determining whether the herpes simplex virus infection is reactivated") and step g) ("determining the rate of reactivation...") of claim 4. However, in order to expedite issuance of a patent, Applicant has amended claims 1 and 4 by adding steps h), including therein a limitation addressing the asserted omitted step.

Claims 1, 4, and 6-13 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 6. It is asserted that the specification is not enabled because the term "inhibit" does not require that the composition completely prevent reactivation. Claims 1 and 4 have been amended consonant with the Examiner's suggestions.

Claims 1, 4, 6, and 8-15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 7. It is asserted that the specification is not enabled as to any form of radiation other than ultraviolet radiation. Claims 1 and 4 are amended in response to this ground of rejection. Claim 7 is further amended consonant with the amendment to claims 1 and 4.

Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 8. It is asserted that the specification is not enabled for methods involving the use of a statistically insignificant number of animals. It is noted that statistical relevance depends on a variety of factors, including the desired p (or probability) level, the nature of substance treated (predicted efficacy,

etc.), and the like. While a standard 0.05 p value is used for many purposes, other cutoffs may be used depending on the purpose of the study and the desired information outcome. For example, in a therapeutic drug vaccine study it may be desired to use a large number of animals in order to assure high statistical relevance. However, in other studies relevant information may be obtained with few animals, particularly where a binary outcome (yes/no) is required, or the study essentially focuses on the natural history of the drug. Applicant has amended claims 1, 4 and 5 to include a "statistically relevant" limitation in step a) of each.

Claims 1, 4-13, and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 9. It is asserted that the specification provides enablement only for methods wherein the animal is either a SKH-1 or B6129 mouse. This rejection is respectfully traversed. First, it is noted that the Specification also teaches use of Balb/C mice. See Example 15, Specification at 13, lines 1 - 17. This Example specifically states that Balb/C mice were tested, and describes photoreactiviated disease "[i]n all mouse strains tested." See also Specification at 5, lines 4-5 ("Photoreactivated disease was demonstrated in Balb/C and B6129 mouse strains, with reactivation rates approximating 60%.") See also Examples 1 and 2. It is noted that Balb/C mice are the most common of haired laboratory mice, and are the prototypical "laboratory" mice. Accordingly, Applicant respectfully suggests that the Office Action is erroneous in suggesting that reactivation was demonstrated in only two of three types of mice; in fact, the specification demonstrates reactivation in all three types of mice (SKH-1, B6129 and Balb/C).

Applicant has amended claims 1, 4 and 5 to limit "animals" to mice. However, it is submitted that the Specification is enabling for "mice" generally, given that at least three different strains are disclosed, and all strains tested were suitable. While not formally of record, since filing the application Applicant has validated the method of the invention in additional strains of mice, and can submit a declaration to that effect. The references with respect to Norval et al. and Harbour et al. are simply not relevant, given that they did not use the methods taught by Applicant. Further, it is exceeding simple to determine the

suitability of any mouse strain simply by testing against a strain known to work, such as any of SKH-1, B6129 or Balb/C. Accordingly, the claim as amended is fully enabled by the specification.

Claims 5, 6, 8, 10, 11 and 15 rejected under 35 U.S.C. § 112, first paragraph -- Office Action paragraph numbered 10. It is asserted that the claims "do not allow one of ordinary skill in the art to determine whether the composition has UV protection activity or an anti-viral activity." This ground of rejection is respectfully traversed. Claim 5 is drawn to a "method of determining the effectiveness of an ultraviolet protectant", and step e) provides for "administering an ultraviolet protectant to the animal." Thus claim 5 is drawn to a method of testing a substance which has already been determined, by means not relevant to claim 5, to be an "ultraviolet protectant." The method of claim 5 is test the "effectiveness" of the ultraviolet protectant. See, e.g., Specification at 3, lines 3-4, "sunscreens and other UVR protectants." See also Example 20, Specification starting at 14, line 32 and Example 24, Specification at 15, starting at line 30. Whether anti-viral agents might be effective if applied topically does not affect enablement as to a method of a determining effectiveness of a compound independently determined to be an "ultraviolet protectant." Put another way, claim 5 does not purport to determine whether or not a given compound is an ultraviolet protectant; rather, claim 5 provides a method for determining the effectiveness of a compound already categorized as an ultraviolet protectant. The underlying mechanism of action of the "ultraviolet protectant" does not form a part of the claim, and is not directly relevant to the method of the claim.

Claims Rejections 35 U.S.C. § 103

Claims 1, 4 and 6-13 rejected under 35 U.S.C. § 103 as being unpatentable over the teachings of Norval et al. in view of Wright and further in view of Spruance et al. and Rooney et al. Applicant respectfully traverses this ground of rejection. Initially, Applicant notes that no less than four separate references are combined for this obviousness rejection. These references, when each is considered for the disclosure thereof, actually teach away from Applicant's invention. Initially, and of critical importance, it is noted that the Norval et al. reference specifically developed the "hypothesis ... that u.v.-irradiation

before primary infection with HSV induces a suppressive immune response to the virus which affects the virus-host interaction and accounts for a high incidence of recrudencent lesion on subsequent stimulus." (Abstract, *J. Gen. Virol.* 68: 2693, emphasis added.) This teaching was adopted and reinforced by Spruance, who in discussing the Norval et al. reference state that a murine model in which UV exposure 3 days prior to primary infection "was postulated to induce a suppressive immune response and to alter the virus-host interaction." Thus Norval et al., both independently and as interpreted by Spruance, stand for the proposition that UV exposure prior to primary infection is necessary. This directly contradicts the teaching of Applicant, and teaches away from Applicant's invention.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); see generally MPEP § 2141.02. As the Federal Circuit in *Norton* stated, with respect to a mechanical invention, "[b]ecause that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art." 713 F.2d at 785 (citations omitted). The same rule applies here. Both Norval et al. and Spruance contain "understandings and expectations" contrary to Applicant's invention, and thus cannot properly be applied in an obviousness rejection under section 103.

It is further noted that Norval et al. does not disclose or suggest Applicant's invention, where UV radiation is the only factor for inducing reactivation. See, e.g., Norval et al., Tables 3 and 4 (at pages 2696 and 2697), where the "triggering factors" were "tape strip + u.v.-UCA" (Table 3 and 4) or "u.v. + tape strip" (Table 4) ("UCA" is urocanic acid, as taught at page 2694, a "possible photomediator of the immunosuppressive effects of u.v."). Thus in all instances at least "tape stripping" was employed as a "triggering factor;" Applicant specifically teaches away from such methods. See, e.g., Specification at 2, lines 12-22.

Given that Norval et al. and Spruance specifically teach that UV must be employed before primary infection, these references cannot properly be combined with either Wright or Rooney.

Claims 5 and 15 rejected under 35 U.S.C. § 103 as being unpatentable over the teachings of Norval et al, Wright, Spruance et al. and Rooney et al, further in view of the teachings of Rooney II (Lancet). Applicant respectfully traverses this ground of rejection. Rooney II (*Lancet*) is cited for the proposition that a sunblocking agent may prevent UV-light induced reactiviation of recurrent HSV. However, as discussed above the remainder of the references, either alone or in combination, do not suggest or make obvious Applicant's invention as set forth in claims 5 and 15. Specifically, Norval et al. and Spruance both explicitly adopt and teach the hypothesis that UV radiation prior to primary infection is necessary. Accordingly, the combination of Rooney II with the other cited art does not render Applicant's invention obvious.

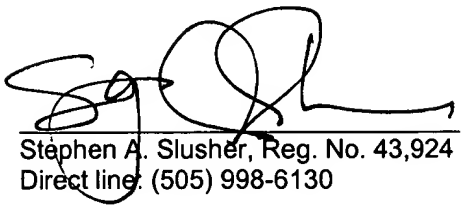
Conclusion

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to July 23, 2004, with the appropriate fee. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

By: 

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